

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES  
OF THE UNIVERSITY OF  
PENNSYLVANIA,

Plaintiffs,

v.

SAREPTA THERAPEUTICS, INC. and  
SAREPTA THERAPEUTICS THREE, LLC,

Defendants.

Civil Action No. 20-1226-RGA

MEMORANDUM ORDER

Before me is Defendants' Motion for Certification for Interlocutory Appeal. (D.I. 40). The issue has been fully briefed. (D.I. 41, 47, 49).<sup>1</sup> For the reasons stated below, I will deny Defendants' motion.

On January 4, 2022, this Court denied Defendants' motion to dismiss. (D.I. 36). Defendants now move for certification for interlocutory appeal, seeking the Federal Circuit's resolution of the following question: "[D]oes *Proveris* hold as a matter of law that the statutory language 'patented invention' in the Safe Harbor excludes patented inventions that are not themselves subject to premarket approval by the FDA?" (D.I. 41 at 2).

An interlocutory appeal is permitted only when the order at issue (1) involves a controlling question of law upon which there is (2) substantial ground for difference of opinion

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<sup>1</sup> Only Plaintiff REGENXBIO has filed an opposition to Defendants' motion. (D.I. 47). Plaintiff The Trustees of the University of Pennsylvania has not taken a position on the motion. (See D.I. 49 at 1).

as to its correctness, and (3) if appealed immediately, may materially advance the ultimate termination of the litigation. 28 U.S.C. § 1292(b). “Interlocutory appeal is meant to be used sparingly and only in exceptional cases where the interests cutting in favor of immediate appeal overcome the presumption against piecemeal litigation.” *Microsoft Mobile Inc. v. Interdigital, Inc.*, 2016 WL 8302609, at \*1 (D. Del. June 13, 2016) (internal citation omitted).

Defendants have failed to show that an interlocutory appeal will materially advance the ultimate termination of this litigation. In denying the motion to dismiss, this Court held that under *Proveris*, a patented product that is not subject to FDA premarket approval is not a “patented invention” under § 271(e)(1). (D.I. 36 at 8). This Court did not reach Plaintiffs’ alternative argument that there were factual disputes regarding whether Defendants engaged in commercial activities outside the scope of the safe harbor. (See D.I. 20 at 11–12; D.I. 22 at 2–3). Thus, even if the Federal Circuit agrees with Defendants on the *Proveris* issue, factual issues—including whether Defendants engaged in commercial activity—would still need to be adjudicated. An interlocutory appeal certainly would not result in the immediate dismissal of the lawsuit, and I am not convinced that it will significantly narrow the scope of this litigation.

While there may be room for appellate clarification on the issue identified by Defendants, resolution of this issue is best reserved for appeal following a final judgment in this case.

Defendants’ Motion for Certification for Interlocutory Appeal (D.I. 40) is **DENIED**.

Entered this 23<sup>rd</sup> day of May, 2022.

  
United States District Judge